VOCO

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JUL 2 4 2008

VOCO GmbH · Postfach 7 67 · 27457 Cuxhaven · Germany

K080814

510(k) SUMMARY

Contact: M. Th. Plaumann

Date prepared: March 20, 2008

Trade or proprietary name: **VOCO Profluorid Varnish**

Classification name: Varnish, Cavity (872.3260)

Predicate device:

Duraphat	K945794
Fluoride Varnish	K031932

Device description:
VOCO Profluorid Varnish is a fluoride containing dental varnish for application to enamel surfaces as well as dentin for the treatment of hypersensitive teeth and for use as a cavity liner under amalgam restorations. **VOCO Profluorid Varnish** will adhere to wet surfaces and is tolerant to moisture and saliva.

Intended use: **VOCO Profluorid Varnish** is intended for use as a desensitizing agent for the treatment of hypersensitive teeth, for sealing the dentinal tubules for cavity preparations or on sensitive root surfaces or to line cavity preparations under amalgam restorations.

Technological characteristics: All of the components of **VOCO Profluorid Varnish** are found in the legally marketed devices K945794 (Duraphat), K031932 (Fluoride Varnish) and K961893 (Duraflor Cavity Varnish) with the exception of ethyl cellulose which has been cleared by FDA as a food additive permitted for direct addition to food for human use (21 CFR 172.868).

The prior use of all of the components of **VOCO Profluorid Varnish** in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary. We believe that the prior use of the components of **VOCO Profluorid Varnish** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **VOCO Profluorid Varnish** for the intended use.

VOCO GmbH, March 20, 2008

Plaumann

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. M. Th. Plaumann
Managing Board
VOCO GmbH
Anton-Flettner-Strasse 1-3
Cuxhaven
GERMANY D-27472

JUL 24 2008

Re: K080814
Trade/Device Name: VOCO Profluorid Varnish
Regulation Number: 21CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: July 15, 2008
Received: July 18, 2008

Dear Mr. Plaumann:

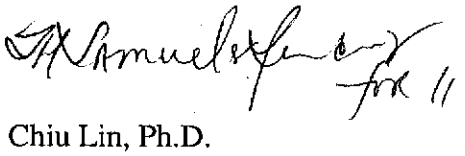
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K086814

Device Name: **VOCO Profluorid Varnish**

Indications for Use:

VOCO Profluorid Varnish is intended for use as
- Treatment of hypersensitive teeth,
- Sealing the dentinal tubules for cavity preparations or on sensitive root surfaces
- Cavity liner under amalgam restorations

Prescription Use __X___ OR **Over-The-Counter Use** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K086814